K032215

510(k) Summary

Date
July 17, 2003

Submitter
PLUS Orthopedics
6055 Lusk Blvd
San Diego, CA

AUG - 8 2003

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Total knee

Classification name
Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
(per 21 CFR section 888.3560)

Equivalent Device
The VKS/TC-PLUS Revision Knee is equivalent to the VKS Total Knee (K022204) in terms of materials, articulating surface geometry, constraint and indications, and the RT-PLUS Modular Knee (K023667) in terms of modular stems and augmentation blocks.

Device Description
The VKS/TC-PLUS Revision Knee is a tri-compartmental knee consisting of a femoral component, tibial baseplate, tibial insert, femoral and tibial augmentation blocks and intramedullary stems.

The VKS/TC-PLUS Revision femoral component is available in five size and right and left configurations. It has a post in the box into which is machined a female Morse type taper to receive an intramedullary stem. It is also configured to received posterior and distal augmentation blocks.

The VKS/TC-PLUS Revision tibial baseplate has five sizes, right and left, and has the same outer profile as the VKS baseplates cleared in K022204. The tibial insert locking mechanism is the same as the VKS Knee. The inferior surface of the baseplate has a short post with a female type taper machined into it to receive modular stems and a hole through the baseplate to receive a screw to augment the baseplate/stem connection. The stems are the same as used on the femoral component. The inferior surface of the baseplate also has two fins that extend posterior/laterally from the post.

The same ultra-congruent insert cleared with the VKS Knee under K022204 is used with the VKS/TC-PLUS Revision Knee.

The femoral augmentation blocks are available in distal and posterior configurations, 5mm and 10mm thickness. The tibial augmentation blocks are available in half blocks so that medial, lateral or full augmentation can be achieved. They are also available in 5mm and 10mm thickness.

Intended Use
The VKS/TC-PLUS Revision Knee is intended for use in patients who are candidates for revision knee arthroplasty where the collateral ligaments are intact. It is not indicated when significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, or connective tissue disorders. It is for cemented use only.

Summary of Technological Characteristics Compared to Predicate Device
Engineering analysis indicates that the VKS/TC-PLUS Revision Knee is as strong as its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

PLUS Orthopedics
c/o Mr. J.D. Webb
Authorized Contact Person
1001 Oakwood Blvd
Round Rock, TX 78681

Re: K032215
Trade/Device Name: VKS/TC-PLUS Revision Knee
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: July 17, 2003
Received: July 21, 2003

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known):_____ K032215

Device Name: VKS/TC-PLUS Revision Knee

Indications for Use:

VKS/TC-PLUS Revision Knee
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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____(Division Sign-off)
Division of General, Neurological and Restorative Devices

510(k) Number_____

Prescription Use ____
(per 21 CFR 801.109) OR Over-the-Counter Use ____

(Optional format 1-2-96) _____

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032215